Report of the announced inspection of medication safety at the Mater Misericordiae University Hospital, Dublin.

Date of announced inspection: 15 November 2016
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About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high-quality and safe care for people using our health and social care services in Ireland. HIQA’s role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered.

HIQA aims to safeguard people and improve the safety and quality of health and social care services across its full range of functions. HIQA’s mandate to date extends across a specified range of public, private and voluntary sector services. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, HIQA has statutory responsibility for:

Setting Standards for Health and Social Services — Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.

Regulation — Registering and inspecting designated centres.

Monitoring Children’s Services — Monitoring and inspecting children’s social services.

Monitoring Healthcare Safety and Quality — Monitoring the safety and quality of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.

Health Technology Assessment — Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.

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Report of the announced inspection of medication safety at the Mater Misericordiae University Hospital
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1. Introduction

Medications are the most commonly used intervention in healthcare, and advances in medication usage continue to play a key role in improving patient treatment success. However, where medicines are used, the potential for error, such as in prescribing, administering or monitoring, also exists. While most medication errors do not result in patient harm, medication errors have, in some instances, the potential to result in catastrophic harm or death to patients.

Medication related events were the third most common type of adverse event recorded in the Irish National Adverse Events Study. Medication safety has also been identified internationally as a key focus for improvement in all healthcare settings and it is estimated that on average, at least one medication error per hospital patient occurs each day.

HIQA’s medication safety monitoring programme, which commenced in 2016, aims to examine and positively influence the adoption and implementation of evidence-based practice in public acute hospitals around medication safety. HIQA monitors medication safety against the National Standards for Safer Better Healthcare to determine if hospitals have effective arrangements in place to protect patients from harm related to medication use.

An expert advisory group was formed to assist with the development of this medication safety monitoring programme. The advisory group membership included patient representation, alongside members with relevant expertise from across the Irish health service. Specific lines of enquiry were developed to facilitate medication safety monitoring. The lines of enquiry which are aligned to HIQA’s National Standards for Safer Better Healthcare are included in Appendix 1 of this report. Further information can be found in a Guide to the Health Information and Quality Authority’s Medication Safety Monitoring Programme in Public Acute Hospitals 2016 which is available on HIQA’s website: www.hiqa.ie

An announced medication safety inspection was carried out at the Mater Misericordiae University Hospital by Authorised Persons from HIQA; Sean Egan, Shane Grogan, Kathryn Hanly and Aoife Lenihan. The inspection was carried out on 15 November 2016 between 10:30hrs and 17:00hrs.

Interviews were held in the Mater Misericordiae University Hospital with the following groups:

- Group one: a medical senior house officer, a surgical intern and basic grade pharmacist.
- Group two: the Chair of Drugs and Therapeutics Committee, the Chief Pharmacist and an additional member of the pharmacy management team, the Medication Safety Coordinator, and the Head of Risk Management.
Group three: the Chief Executive Officer, the Clinical Director and the Director of Nursing.

Inspectors visited the following clinical areas and spoke with staff regarding medication safety and reviewed documentation:

- St John’s Ward (medical ward)
- St Vincent’s Ward and St Vincent’s Day Unit (oncology/haematology)

In addition a survey was conducted among outpatients in the Outpatients Department.

HIQA would like to acknowledge the cooperation of staff who facilitated and contributed to this announced inspection and the hospital outpatients who spoke with inspectors.
2. Findings at the Mater Misericordiae University Hospital

The following sections of this report present the general findings of this announced inspection which are aligned to the inspection lines of inquiry.

2.1 Governance and risk management

**Lines of enquiry:**

- Patient safety is enhanced through an effective medication safety programme underpinned by formalised governance structures and clear accountability arrangements.
- There are arrangements in place to identify report and manage risk related to medication safety throughout the hospital.

The Mater Misericordiae University Hospital had formalised governance arrangements and organisational structures with clear lines of accountability in place to support the safe use of medications. The Drugs and Therapeutics Committee was responsible for the governance of the hospital’s medication management system and for ensuring its safety. It was evident that medication safety was strongly supported at executive level in the hospital. Moreover, there was evidence that the Hospital Board actively sought assurance in relation to medication safety. Inspectors were informed that quality, safety and risk including medication safety were standing items for discussion at Board meetings.

The organogram showing lines of communication for medication safety, provided by the hospital to HIQA, showed that the Drugs and Therapeutics Committee had a dual reporting relationship to the Medical Executive* and to the clinical directorates. A copy of this organogram is included in Appendix 2. It was explained to the inspectors that the clinical directorate system was still evolving. While this arrangement was developing, existing reporting lines to the Medical Executive remained in place. The hospital needs to assure itself that this dual reporting relationship does not create confusion, and that there are reporting lines and accountability structures in line with the National Standards.³

The roles and functions of Drugs and Therapeutics Committee were clearly articulated in the Committee’s terms of reference. The committee had oversight of the medicines management system within the hospital.⁵ The committee benefited from a high level of involvement from pharmacy department staff, in addition to relevant multidisciplinary staff membership from each directorate. However, it was reported that committee member attendance at meetings was variable.

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*Medical Executive: A governance forum chaired and staffed by medical consultants within the hospital.
The hospital also had an established Drug Safety Committee. Operational implementation of the medication programme was effectively facilitated by the Drug Safety Facilitator in conjunction with the Drug Safety Committee. This committee met monthly and reported to a Patient Safety and Risk Management Committee that in turn reported to the Hospital Executive. The Drug Safety Committee did not have a formal reporting relationship with the Drugs and Therapeutics Committee. However, medication safety was a standing item on the Drugs and Therapeutics Committee meeting agenda. Membership of the Drug Safety Committee was multidisciplinary. The committee made recommendations to the Quality and Patient Safety Directorate and the Drugs and Therapeutics Committee concerning system-based approaches to enhance patient safety, in line with evidence-based best practice.

Hospital staff voluntarily reported medication incidents and near misses on a medication variance† form. The Drug Safety Committee reviewed medication incidents and near misses reported in the incident monitoring system. Medication incidents and near misses were tracked and trended to assess progress and to identify emergent medication safety concerns.

Clinical incident reports involving the prescription or administration of medicines were prepared by the Drug Safety Committee and reviewed by the Drugs and Therapeutics Committee throughout the year. A medication variance annual report was prepared by the Drug Safety Committee and distributed throughout the organisation and presented at Grand Rounds‡. Distribution included the:

- Drugs and Therapeutics Committee
- Hospital Board
- Clinical Directorates
- Medical Executive
- Nursing Executive
- Patient Safety and Risk Management Committee
- Quality and Patient Safety Steering Group

The Mater Misericordiae University Hospital’s 2015 medication variance annual report provided a detailed review of medication incidents reported throughout the year and outlined actions undertaken in response to medication incidents and near misses.

There was evidence of significant effort by the Drug Safety Committee, supported by senior management, to provide leadership to support a safer patient culture related

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† The Mater Misericordiae University Hospital define a medication variance as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer. This includes medication errors and near misses.

‡ Grand rounds are formal meetings where physicians and other clinical support and administrative staff discuss the clinical case of one or more patients. Grand rounds originated as part of medical training.
to medication usage. The 2015 medication variance annual report showed medication incidents and near miss reporting had increased by over 50% since 2013, as shown in Figure 1. Studies have found a positive association between increased incident reporting rates and measures of safety culture where an increase in incident reporting was indicative of a positive reporting culture within the hospital.\textsuperscript{6} HIQA note that notwithstanding this positive trend in reporting, the majority of reports were submitted by clinical pharmacists while nursing and medical staff submitted just 14% and 1% of reports respectively.

**Figure 1: Number of medication variances reported annually in the Mater Misericordiae University Hospital 2002- 2015.**

Important lessons can be learned from analysis of medication-related incidents and near misses. Inspectors were informed that medication-related incidents and near misses were analysed and actions were taken to address them with further recommendations made to prevent reoccurrences of such variances. For example, following an incident involving an anticoagulant medication (medication used to treat or prevent blood clots), a new policy was developed, the medication prescribing chart was reviewed, alerts were circulated to relevant hospital staff and prescribing algorithms\textsuperscript{5} were reviewed. In addition, following this incident a review of communication and incident management was performed. An annual plan for medication safety was also formulated by the Drug Safety Committee based on an evaluation of identified issues.

Following the analysis of medication variances, the hospital identified a list of high alert medications that present a heightened risk of causing significant patient harm if not used correctly. Anticoagulant medication, opioids (strong pain killing medication)

\textsuperscript{5} Prescribing algorithms include decision tree approaches to healthcare treatment (e.g., if symptoms A, B, and C are evident, then use treatment X)
and insulin were the most common medication categories reported in variances in recent years. Inspectors observed a suite of policies, procedures and guidelines related to the use of high alert medicines and high-risk practices related to the use of medicines.

2.2 Audit and evaluation

**Line of enquiry:**
- The effectiveness of medication management systems are systematically monitored and evaluated to ensure they are effective.

Medication safety audit results and relevant data were used as the basis for decision-making, action and change. Measures used by the hospital included retrospective patient healthcare record review, direct observation, risk assessment and voluntary reporting of adverse events.

Inspectors were informed that audits were completed following the introduction of new medication-related services. For example, the impact of electronic prescribing on the quality and safety of chemotherapy prescribing in oncology and haematology services was audited. In addition, the medication reconciliation service at the hospital had been audited in line with the World Health Organization’s guidelines for medication reconciliation**. In October 2016, 78% of patients admitted through the hospital Emergency Department who were over 65 years old had their medications reconciled during clinical pharmacy service hours. Preliminary analysis of this process identified 1.5 discrepancies per patient, a rate consistent with that found in studies conducted internationally. Inspectors were informed that these findings were presented to senior management and that other members of the multidisciplinary team were appreciative of the new service.

Medication audit reports were reviewed by the Drug and Therapeutics Committee. Inspectors were informed that staff were encouraged to register audits to a centralised register of audits which was maintained by the Quality and Patient Safety Directorate.

**Medicines reconciliation is a formal, systematic process for obtaining a current and accurate list of medicines a patient was taking when admitted to hospital, known as a best possible medication history, and reconciling this history against the patient’s medicines prescribed at admission, transfer and discharge on the medication chart.**
2.3 Medication safety support structures and initiatives

Line of enquiry:
- Hospitals develop effective processes to promote medication safety that are implemented and supported by clear and up-to-date policies, procedures and or protocols.

The Drugs and Therapeutics Committee had established and maintained a prescriber’s guide\textsuperscript{††} containing the hospital medication formulary\textsuperscript‡‡. Decisions to add or remove medications from the formulary were guided by written criteria. Documentation reviewed during the course of the inspection indicated that amendments to the formulary were considered at Drugs and Therapeutics Committee meetings. Decisions with significant budgetary impact were additionally overseen by senior hospital management.

All clinical areas had an assigned clinical pharmacist. International studies support the role of clinical pharmacists in hospital wards in preventing adverse drug events.\textsuperscript{7,8,9,10,11,12} Clinical pharmacists reviewed inpatient medication prescription charts throughout the hospital to prevent, identify, intercept, and report medication prescribing-related incidents. This service was provided from Monday to Friday. Medication prescription charts were annotated by clinical pharmacists as necessary to provide additional clarity. Clinical pharmacists had the authority to cancel medication prescriptions where therapeutic duplication or incorrect prescribing was identified. However, inspectors were informed that clinical pharmacists did not routinely perform medication reconciliation as part of clinical duties at ward level.

The hospital introduced a formal structured pharmacy-led medication reconciliation service in July 2016 for all patients over 65 years old who were admitted to the hospital through the Emergency Department. Medication reconciliation at time of admission is a systematic process conducted by an appropriately trained individual, to obtain an accurate and complete list of all medications that a patient was taking prior to admission.\textsuperscript{13,14,15,16} This history is compared to medications prescribed at admission in order to identify and resolve any discrepancies. A formalised medication reconciliation service was not provided at patient discharge.

Medication safety bulletins were developed by the Drug Safety Committee in response to medication incidents and near misses reported locally in addition to

\textsuperscript{††} Prescribers’ Guide – a guide that contains the agreed Mater Misericordiae University Hospital’s policies involving medications as well as the hospital medication formulary.

\textsuperscript‡‡ A formulary is a hospital’s approved list of medicines that staff can use as a reference document to ensure safe and cost-effective prescribing.
guidance, alerts, recalls and recommendations issued by external bodies. Efforts were made to share learning with other hospitals nationally.

Inspectors saw examples of quality improvement initiatives that had been implemented and evaluated. Staff demonstrated the use of an electronic medication prescribing, compounding and administration system used in the oncology/haematology service to support cancer treatment planning, therapy monitoring and the preparation of cytotoxic medications. This system was designed to minimise errors in intravenous medication preparation and administration, through bar code verification of prescribed medications, in this complex speciality.

Inspectors were informed of proactive measures to reduce the incidence of medication errors associated with high-alert medications. For example, the endocrinology team conducted daily insulin management rounds to prescribe and monitor inpatient insulin regimes. It was reported by staff that this was a positive development. In evaluating the overall impact of an intervention such as this, it is important that the possible risks of such specialisation; for example, through the potential for delay in access to required staff, are fully mitigated.

Open disclosure occurs when staff in the health and social care service communicate with patients in an open and honest manner when things go wrong with patient care.3,17 Inspectors were informed that the hospital had a process in place to promptly inform patients when medication-related incidents occurred. Staff spoken with were familiar with the hospital’s open disclosure policy.

The Mater Misericordiae University Hospital was also participating in the Health Service Executive (HSE) Quality Improvement Division venous thromboembolism quality improvement collaborative. This is a collaborative among multidisciplinary teams in Irish adult acute public and voluntary hospitals who are working together to achieve appropriate thromboprophylaxis for their hospital’s inpatients, to reduce the risk of venous thromboembolism and to minimize harm and expenditure associated with unnecessary thromboprophylaxis. Documentation reviewed indicated that participation in the collaborative was supported by the hospital’s Quality and Patient Safety Directorate.

Inspectors were informed that nursing metrics and serious reportable events were reported to hospital group level; however, medication safety quality improvement activities were not routinely shared at hospital group level.
2.4 Person-centred care

Line of enquiry:
- Patients and or carers are informed about the benefits and associated risks of prescribed medications in a way that is accessible and understandable.

The Mater Misericordiae University Hospital had systems in place to support the provision of patient information and education in relation to medication usage. This included the availability of written patient information leaflets that were available at the point of care. Inspectors were informed that clinical pharmacists provided education to all patients prescribed oral anticoagulant medication.

Patients should be well informed about any medications they are prescribed and any possible side-effects. This is particularly relevant for those patients who are taking multiple medications. As part of this inspection, HIQA asked a small sample of hospital outpatients attending the Outpatients Department to complete an anonymised questionnaire in relation to prescribed medications. The questionnaire was completed by 18 people who had been inpatients at the Mater Misericordiae University Hospital within the past year and who were newly prescribed regular medications. Of the 18 people surveyed:

- 56% said that, other than being provided with a prescription form to take to their local pharmacy or GP, they had not been given a list that outlined what medicines they were on in a way they could understand.
- 72% said that a staff member had explained the purpose of new medication in a way that they could understand.
- 44% said that a staff member told them about possible medication side effects to look out for following discharge home.
- 67% said they received instruction on how to take their medications at home.

It is acknowledged that this was a small sample of outpatients and therefore was not representative of all recently discharged patients taking prescribed medication. This information does however, provide some information about outpatients understanding and could be expanded upon and used to identify opportunities for improvement.

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§§ Patient-held medication lists are completed by a healthcare professional to accurately list all medications the patient is taking at time of discharge.
2.5 Policies, procedures, guidelines and access to information

Lines of enquiry:

- Hospitals develop effective processes for medication management that are implemented and supported by clear and up to date policies, procedures and/or protocols.
- Essential information supporting the safe use of medicines is readily available in a user friendly format and is adhered to when prescribing, dispensing and administering medications.

The Pharmacy Department in conjunction with the Drugs & Therapeutics Committee and the Drug Safety Committee had developed and implemented an extensive suite of medication management policies, procedures, protocols and guidelines to support safe medication management systems within the hospital. All medication-related policies, procedures and guidelines were approved by the Drugs and Therapeutics Committee prior to implementation. Medication policies, procedures, protocols and guidelines were readily available to staff on the hospital intranet and through the hospital’s document management system.

A medicines information service was provided by the Pharmacy Department. This service provided ready access to expert advice in the management of medication-related queries, and was open to all staff. It was also involved in the development of medication protocols and prescribing guidelines to optimise safe and effective medication use while enhancing patient care. Clinical pharmacists at ward level also provided key information on medications to medical, nursing and other staff, as well as to patients.

The Mater Misericordiae University Hospital prescribers’ guide provided prescribing guidance for relevant staff. The prescribers guide contained a range of care plans, prescribing algorithms, a list of hospital formulary medications, links to medications protocols and general prescribing information.

In addition, a number of decision support tools were available to staff in clinical areas including intravenous medication monographs***, medication treatment protocols, up-to-date medicines reference material and online evidence-based clinical decision support resources for reference through the library on the hospital intranet.

*** An approved set of standardised and approved instructions for the correct preparation and administration of intravenous medication, that have been designed to reduce the risk of error, and that are specifically tailored to the intravenous medicines stocked within the hospital.
2.6 Training and education

Line of enquiry:
- Safe prescribing and drug administration practices are supported by mandatory and practical training on medication management for relevant staff.

Medication safety awareness in the hospital was promoted through staff communication including circulation of medication safety alerts and through medication safety education. Inspectors were informed that medication safety alerts were disseminated to staff by way of the hospital intranet. In addition, new medicines management information was cascaded to relevant staff through awareness campaigns. For example, in response to the number of variances reported involving anticoagulant medication there was a large-scale educational drive around the use of direct acting oral anticoagulants throughout 2015.

The Mater Misericordiae University Hospital had developed a medication safety electronic learning package which included ‘a guide to high risk drugs’. This electronic learning package was brought to the attention of all new staff during induction. Nursing, medical and pharmacy staff were encouraged to undertake this programme. However, inspectors were informed that not all staff had completed the e-learning programme.

All nurses due to commence employment in the hospital completed an intravenous medication workshop. Nurses employed in clinical practice were required to attend a medication update every two years as per the policy on the administration of IV infusions and drugs. This update included an overview of medication errors and medication safety practices within the organisation.

There was an ongoing education programme in the hospital for medication safety that formed part of an overall strategy to increase awareness of the importance of medication safety. This was specific to staff disciplines including medical consultants, non-consultant hospital doctors, nurses, clinical pharmacists and undergraduate students.

The Pharmacy Department provided medication prescribing education to medical undergraduates as part of the University College Dublin Professional Completion Module. The Pharmacy Department also actively contributed to national initiatives and linked in with other hospitals to share learning.
3. Conclusion

Medications represent the primary measure for treatment intervention in hospitalised patients. Error associated with medication usage constitutes one of the major causes of patient harm in hospital. Medication-related events were the third most common type of adverse event recorded in the recently published Irish National Adverse Events Study. Medication safety should therefore be a priority area for all acute hospitals as they seek to ensure a high quality and safe service for patients.

The Mater Misericordiae University Hospital had established governance arrangements in addition to systems, processes and practices to support medication safety. It was evident that this had been progressed over a significant period of time, driven by effective local leadership and executive management support and resource allocation. Moreover, measures implemented by the Hospital’s Board to actively seek assurance in relation to medication safety, a known area of high risk to patients in acute hospitals, were notable.

Hospital management should build on their work to date to develop a medium to long-term medicines safety strategy that sets out a clear vision for medication safety across the organisation. In the absence of national guidance in this area, international guidelines which outline best practice in relation to medication safety governance and improvement are available, and should be considered by staff responsible for patient safety in the hospital setting.

There was evidence of significant effort by the Drug Safety Committee, supported by executive management, to provide leadership to support a safer patient culture related to medicines usage. The hospital promoted an open reporting culture and a process for learning from medication-related incidents and near misses. The hospital should continue efforts to improve rates of incident and near miss reporting by medical, nursing and other relevant staff.

Analysis of medication variances has enabled the Drug Safety Committee at the hospital to target improvement efforts and system changes to reduce the likelihood of reoccurrences of medication-related incidents. Recommendations from the drug safety committee focused on changes in systems, processes or products, rather than solely targeting individual performance. This approach reflects best practice.

The medications reconciliation service provided in the Emergency Department was an example of good practice. Key to the success of implementing medication reconciliation at all transitions of care is first to have this process working effectively at the patient admission stage. The Commission on Patient Safety and Quality Assurance recommended as a priority that medication reconciliation be provided to all patients at all transfer of care stages. Notwithstanding the considerable resource implications and challenges involved, the hospital should seek to explore the
expansion of this service to implement admission to discharge medication reconciliation across the continuum to include all patients.\textsuperscript{13,16} Given the benefits identified by the hospital regarding the medication reconciliation service, and with an average of 1.5 discrepancies per patient rectified, a good case for expansion of the medication reconciliation service to include all transitions of care and discharge may exist.

Studies have highlighted the need for quality improvement in inpatient diabetes care.\textsuperscript{19} The daily insulin management rounds, conducted by the endocrinology team, provided specialist advice on the ongoing management of insulin regimes for diabetic patients. This was an example of good practice. However, it is important that the effectiveness of the daily insulin management rounds are regularly monitored and evaluated to ensure the service does not contribute to a de-skilled workforce or fragmented care.

The patient survey showed that there were opportunities for improvement in how patients are informed about medications they are prescribed and any possible side-effects. This is particularly relevant for those patients who are taking multiple medications. Efforts should be made to further improve communication with patients about their medications.\textsuperscript{20}

The hospital should collaborate further within the new hospital group structure, to share good practice pertaining to medication safety and to develop and implement policies and practices for medication management.
4. References


††† All online references were accessed at the time of preparing this report. Web addresses may change over time.


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5. Appendices

Appendix 1 Lines of enquiry and associated *National Standard for Safer Better Healthcare*²

<table>
<thead>
<tr>
<th>Area to be explored</th>
<th>Line of enquiry***</th>
<th>National Standards for Safer Better Healthcare</th>
</tr>
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<tbody>
<tr>
<td>Clear lines of accountability and responsibility for medication safety</td>
<td>1. Patient safety is enhanced through an effective medication safety programme underpinned by formalised governance structures and clear accountability arrangements.</td>
<td>3.1, 5.1, 5.2, 5.4, 5.5, 5.6, 5.8, 5.9, 5.10, 7.1</td>
</tr>
<tr>
<td>Patient involvement in service delivery</td>
<td>2. Patients and or carers are informed about the benefits and associated risks of prescribed medicines in a way that is accessible and understandable.</td>
<td>1.4, 1.5, 1.7, 3.1, 4.1</td>
</tr>
<tr>
<td>Policies procedures and guidelines</td>
<td>3. Hospitals develop effective processes to promote medication safety that are implemented and supported by clear and up-to-date policies, procedures and or protocols.</td>
<td>2.1, 3.1, 3.2, 3.3, 3.5, 3.6, 3.7, 5.8, 5.11, 8.1</td>
</tr>
<tr>
<td>Risk management</td>
<td>4. There are arrangements in place to identify, report and manage risk related to medication safety throughout the hospital.</td>
<td>3.1, 3.2, 3.3, 3.5, 3.6, 3.7, 5.8, 5.10, 5.11, 8.1</td>
</tr>
<tr>
<td>Audit and evaluation</td>
<td>5. The effectiveness of medication management systems are systematically monitored and evaluated to ensure they are effective.</td>
<td>2.8, 3.1, 5.8, 8.1</td>
</tr>
<tr>
<td>Education and training</td>
<td>6. Safe prescribing and drug administration practices are supported by mandatory and practical training on medication management for relevant staff.</td>
<td>6.2, 6.3</td>
</tr>
<tr>
<td>Access to information</td>
<td>7. Essential information of the safe use of medications is readily available in a user-friendly format and is adhered to when prescribing, dispensing and administering medications.</td>
<td>2.5, 8.1</td>
</tr>
</tbody>
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*Lines of enquiry are the key questions or prompts that inspectors use to help inform their inspection, assessment or investigation.*
Appendix 2: Mater Misericordiae University Hospital organogram showing lines of communication for medication safety.
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